

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Mail No. EV 456356880 US, in an envelope addressed to: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22304-1450, on the date shown below.

Dated: September 2, 2005

Signature: *Georgina Ilatos*

(Georgina Ilatos)

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

ATTORNEY'S DOCKET NUMBER

404172000300

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)

10/511,229

INTERNATIONAL APPLICATION NO. .
PCT/IT02/00231

INTERNATIONAL FILING DATE
12 April 2002

PRIORITY DATE CLAIMED
12 April 2002

TITLE OF INVENTION

PURIFIED SUBFRAGMENT CODIFYING FOR NEUROAMINIDASE, RECOMBINANT NEUROAMINIDASE AND ITS USE IN ZOOPROPHYLAXIS

APPLICANT(S) FOR DO/EO/US

Ilaria CAPUA et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
 2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
 3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
 4. ☐ The US has been elected (Article 31).
 5. ☐ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
 6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☐ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
 7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
 8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
 9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
 10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).
- Items 11 to 20 below concern document(s) or information included:**
11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98. (3 pages)
 12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
 13. ☐ A preliminary amendment.
 14. ☐ An Application Data Sheet under 37 CFR 1.76.
 15. ☐ A substitute specification.
 16. ☐ A power of attorney and/or change of address letter.
 17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
 18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
 19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.


U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/511,229	INTERNATIONAL APPLICATION NO. PCT/IT02/00231	ATTORNEY'S DOCKET NUMBER 404172000300
20. <input checked="" type="checkbox"/> Other items or information: PTO/SB/08a/b + copy (6 pages), thirty-seven (37) references, Return Receipt Postcard		
The following fees have been submitted		
21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.492(a)) \$300	CALCULATIONS	PTO USE ONLY
	\$ 0.00	
22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 All other situations \$200	\$ 0.00	
23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB \$400 All other situations \$500	\$ 0.00	
TOTAL OF 21, 22 and 23 =		\$ 0.00
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.		
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)
0 - 100 =	0 /50 =	0
		x \$250.00
		\$ 0.00
Surcharge of \$130 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).		\$ 0.00
CLAIMS	NUMBER FILED	NUMBER EXTRA
Total claims	14 - 20 =	0
Independent claims	2 - 3 =	0
		+ 360.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)		0.00
TOTAL OF ABOVE CALCULATIONS =		\$ 0.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.		
SUBTOTAL =		\$ 0.00
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).		0.00
TOTAL NATIONAL FEE =		\$ 0.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property		0.00
TOTAL FEES ENCLOSED =		\$ 0.00
		Amount to be refunded: \$ 0.00
		Amount to be charged \$ 0.00

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 03-1952. ~~A duplicate copy of this sheet is enclosed.~~
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO -2038

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:


SIGNATURE

Janet Xiao
NAME

CUSTOMER NUMBER: 25226

55,748
REGISTRATION NUMBER

Rec'd POT/PTO 02 SEP 2005

JS

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV 456356880 US, in an envelope addressed to: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: September 2, 2005

Signature:

Georgia Matos
(Georgia Matos)

Patent

Docket No. 404172000300

Client Reference No. LABBA/P29480US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Ilaria CAPUA et al.

Serial No.: 10/511,229

International Filing Date: April 12, 2002

International Application No.: PCT/IT02/00231

For: PURIFIED SUBFRAGMENT
CODIFYING FOR NEUROAMINIDASE,
RECOMBINANT NEUROAMINIDASE
AND ITS USE IN ZOOPROPHYLAXIS

Examiner: Not Yet Assigned

Group Art Unit: 1645

**INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98**

Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of non-patent literature are submitted herewith. The Examiner is requested to make these documents of record.

This Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☒ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
 - ☐ A fee is required. A check in the amount of ___ is enclosed.
 - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of ___ is enclosed.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist;

Application Serial No. 10/511,229

Patent
Docket No. 404172000300
Client Reference No. LABBA/P29480US

(iii) the information, protocols, results and the like reported by third parties are accurate or enabling;
or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 404172000300.

Dated: September 2, 2005

Respectfully submitted,

By 
Janet Xiao

Registration No.: 55,748
MORRISON & FOERSTER LLP
755 Page Mill Road
Palo Alto, CA 94304-1018
(650) 813-5736

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/511,229
				Int'l Filing Date	April 12, 2002
				First Named Inventor	Ilaria CAPUA
				Art Unit	1645
				Examiner Name	Not Yet Assigned
Sheet	1	of	3	Attorney Docket Number	404172000300

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	US-6,221,362-B1	04-24-2001	Audonnet et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
	2.	Anonymous. (June 22, 1992). "Council Directive 92/40/EEC of 19 May 1992 Introducing Community Measures for the Control of Avian Influenza," <i>The Council of the European Communities</i> L167:1-18.			
	3.	Anonymous. (December 13, 2002). "Commissione: Decisione Della Commissione del 12 dicembre 2002 Relativa all'Introduzione della Vaccinazione ad Integrazione delle Misure di Lotta Contro le Infezioni da Virus dell'Influenza Aviarie a Bassa Patogenicità in Italia e Recante Misure Specifiche di Controllo dei Movimenti, 2002/975/CE," <i>Official Journal of the European Commission</i> L337:87-92. (In Italian.)			
	4.	Anonymous. (September 30, 2004). "Commission Decision of 29 September 2004 on Introducing Vaccination to Supplement the Measures to Control Infections with Low Pathogenic Avian Influenza in Italy and on Specific Movement Control Measures and Repealing Decision 2002/975/EC, Decision 2004/666/EC," <i>Official Journal of the European Union</i> L303:35-44.			
	5.	Brugh, M. et al. (September 3-5, 1986). "Immunization of Chickens Against Influenza With Hemagglutinin-Specific (H5) Oil Emulsion Vaccine," <i>Proceedings of the Second International Symposium on Avian Influenza</i> , Athens, GA, September 3-5, 1986, pp. 283-289.			
	6.	Capua, I. et al. (2000). "The Avian Influenza Epidemic in Italy, 1999-2000: A Review," <i>Avian Pathology</i> 29:289-294.			
	7.	Capua, I. et al. (December 23/30, 2000). "Vaccination for Avian Influenza in Italy," <i>The Veterinary Record</i> pg. 751. Vol 147, No 26			
	8.	Capua, I. et al. (2001). Chapters One through Ten <i>In A Colour Atlas and Text on Avian Influenza</i> Papi Editore: Bologna, Italy, 64 pgs.			
	9.	Capua, I. et al. (2002). "Development of a DIVA (Differentiating Infected From Vaccinated Animals) Strategy Using a Vaccine Containing a Heterologous Neuraminidase for the Control of Avian Influenza," <i>Avian Pathology</i> 32:47-55.			
	10.	Capua, I. et al. (February 16, 2002). "Strategies for the Control of Avian Influenza in Italy," <i>The Veterinary Record</i> pg. 223.			
	11.	Capua, I. et al. (August 2003). "The Use of Vaccination as an Option for the Control of Avian Influenza," <i>Avian Pathology</i> 32(4):335-343.			

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

pa-993346

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MH/

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/511,229
				Int'l Filing Date	April 12, 2002
				First Named Inventor	Ilaria CAPUA
				Art Unit	1645
				Examiner Name	Not Yet Assigned
Sheet	2	of	3	Attorney Docket Number	404172000300

12.	Capua, I. et al. (April 2004). "Increased Resistance of Vaccinated Turkeys to Experimental Infection with an H7N3 Low-Pathogenicity Avian Influenza Virus," <i>Avian Pathology</i> 33(2):158-163.
13.	Capua I. et al. (May 15, 2004). "Eradication of Low Pathogenicity Avian Influenza of the H7N3 Subtype from Italy," <i>The Veterinary Record</i> pp. 639-640.
14.	Cattoli, G. et al. (December 2001). "Utilizzo di un Vaccino Eterologo nei Confronti dell'Influenza Aviaria come Vaccino "Marker": Prova di Cross-Protezione e Validazione Preliminare del Test Discriminatorio," <i>Large Animals Review</i> 7(6):97-98. (In Italian.)
15.	Cattoli, G. et al. (2003). "Development and Preliminary Validation of an Ad Hoc N1-N3 Discriminatory Test for the Control of Avian Influenza in Italy," <i>Avian Diseases</i> 47:1060-1062.
16.	Cattoli, G. et al. (March 8-11, 2003). "The H7N3 Avian Influenza Outbreak in Northern Italy in 2002," <i>Proceedings of the 52nd Western Poultry Disease Conference</i> , Sacramento, CA March 8 - 11, 2003, pp. 23-25.
17.	EMBL Accession No. AF208598, "Genetic Analysis of Avian Influenza Virus in Taiwan," created on December 15, 1999, one page.
18.	Garcia, A. et al. (1998). "Efficacy of Inactivated H5N2 Influenza Vaccines Against Lethal A/Chicken/Queretaro/19/95 Infection," <i>Avian Diseases</i> 42:248-256.
19.	Halvorson, D.A. (2002). "The Control of H5 or H7 Mildly Pathogenic Avian Influenza: A Role for Inactivated Vaccine," <i>Avian Pathology</i> 31:5-12.
20.	Johansson, B.E. (1999). "Immunization with Influenza A Virus Hemagglutinin and Neuraminidase Produced in Recombinant Baculovirus Results in a Balanced and Broadened Immune Response Superior to Conventional Vaccine," <i>Vaccine</i> 17:2073-2080.
21.	Johansson, B.E. et al. (1995). "Immunogenicity of Influenza A Virus N2 Neuraminidase Produced in Insect Larvae by Baculovirus Recombinants," <i>Vaccine</i> 13(9): 841-845.
22.	Lee, C-W. et al. (2004). "Generation of Reassortant Influenza Vaccines by Reverse Genetics That Allows Utilization of a DIVA (Differentiating Infected from Vaccinated Animals) Strategy for the Control of Avian Influenza," <i>Vaccine</i> 22:3175-3181.
23.	Madeley, C.R. et al. (2002). "Methods in Virus Diagnosis: Immunofluorescence Revisited," <i>Journal of Clinical Virology</i> 25:121-134.
24.	McNulty, M.S. et al. (September 3-5, 1986). "Inactivated Avian Influenza Neuraminidase-Specific Vaccines in Chickens," <i>Proceedings of the Second International Symposium on Avian Influenza</i> Athens, GA, September 3-5, 1986, pp. 279-282.
25.	Powers, D. C. et al. (September 1996). "Neuraminidase-Specific Antibody Responses to Inactivated Influenza Virus Vaccine in Young and Elderly Adults," <i>Clinical and Diagnostic Laboratory Immunology</i> 3(5):511-516.
26.	Price, P.M. et al. (March 1989). "Complementation of Recombinant Baculoviruses by Coinfection with Wild-Type Virus Facilitates Production in Insect Larvae of Antigenic Proteins of Hepatitis B Virus and Influenza Virus," <i>Proc. Natl. Acad. Sci. USA</i> 86(5):1453-1456.
27.	Rojas, H. et al. (August 10, 2002). "Avian Influenza in Poultry in Chile," <i>The Veterinary Record</i> pp. 188.
28.	Scholtissek, C. et al. (February 2002). "Cooperation Between the Hemagglutinin of Avian Viruses and the Matrix Protein of Human Influenza A Viruses," <i>Journal of Virology</i> 76(4):1781-1786.
29.	Smeltzer, M.A. (March 8-11, 2003). "Control of Low Pathogenic Avian Influenza in Virginia," <i>Proceedings of the 52nd Western Poultry Disease Conference</i> , Sacramento, CA, March 8-11, 2003, pp. 3-4.
30.	Stegeman, A. et al. (December 15, 2004). "Avian Influenza A Virus (H7N7) Epidemic in The Netherlands in 2003: Course of the Epidemic and Effectiveness of Control Measures," <i>The Journal of Infectious Diseases</i> 190:2088-2095.
31.	Suarez, D.L. (2000). "Evolution of Avian Influenza Viruses," <i>Veterinary Microbiology</i> 74:15-27.
32.	Suarez, D.L. et al. (2000). "Immunology of Avian Influenza Virus: A Review," <i>Developmental and Comparative Immunology</i> 24:269-283.

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/511,229
				Int'l Filing Date	April 12, 2002
				First Named Inventor	Ilaria CAPUA
				Art Unit	1645
				Examiner Name	Not Yet Assigned
Sheet	3	of	3	Attorney Docket Number	404172000300

33.	Swayne, D.E. (1999). "Influence of Virus Strain and Antigen Mass on Efficacy of H5 Avian Influenza Inactivated Vaccines," <i>Avian Pathology</i> 28:245-255.	
34.	Swayne, D.E. et al. (2000). "Highly Pathogenic Avian Influenza," <i>Rev. Sci. Tech. Off. Int. Epiz.</i> 19(2):463-482.	
35.	Tumpey, T. M. et al. (2004). "Comparative Susceptibility of Chickens and Turkeys to Avian Influenza A H7N2 Virus Infection and Protective Efficacy of a Commercial Avian Influenza H7N2 Virus Vaccine," <i>Avian Diseases</i> 48:167-176.	
36.	van Oirschot, J.T. (August 27-30, 2000). "Present and Future of Veterinary Viral Vaccinology," <i>Proceedings of the 5th International Congress of the European Society for Veterinary Virology</i> Brescia, Italy, August 27-30, 2000, pp. 18-27.	
37.	van Regenmortel, M.H.V. et al. eds. (2000). <u>Virus Taxonomy: Classification and Nomenclature of Viruses - Seventh Report of the International Committee on Taxonomy of Viruses</u> Academic Press, Inc.: San Diego, CA, 18 pages.	
38.	Wood, J.M. (2002). "Selection of Influenza Vaccine Strains and Developing Pandemic Vaccines," <i>Vaccine</i> 20:B40-B44.	

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MH/

05/15/2008

/Myron Hill/

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

pa- 993346